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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,687	11/02/2005	Garry A. Palmateer	CRA-0001	3729
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BRUNET & CO. LTD.		EXAMINER		
10712 MELROSE DR.		WOOD, AMANDA P		
KOMOKA, ON N0L-1R0				
CANADA		ART UNIT		
		1657		
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NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/531,687	Applicant(s) PALMATEER ET AL.
	Examiner AMANDA P. WOOD	Art Unit 1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 December 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,3-7,9-11, 13-16, 19-22, 25, 27,29, and 86 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,3-7,9-11,13-16,19-22,25,27,29 and 86 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Applicant's response and amendments filed 23 December 2007 have been received and entered.

Claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29, and 86 considered on the merits.

Withdrawn Rejections

In view of Applicant's amendments to the claims, the rejections of claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29, and 86 under 35 U.S.C. 112 have been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-7, 9-11, 13-16, 19-22, 25, 27, 29, and 86 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nelis (US 5,861,270).

A method is claimed for determining the presence and/or quantity of coliform bacteria in a drinking water sample.

Nelis beneficially teaches a two-stage enzymatic method for the detection of coliform bacteria wherein bacteria are concentrated on a membrane filter. Nelis teaches that bacteria are separated from a drinking water sample by concentrating the

bacteria on a membrane filter and placing the filter and bacteria concentrated thereon on a growth medium, which can comprise a liquid growth medium (i.e., a broth) so as to support growth of the bacteria, and adding an inducer for inducing a marker enzyme (i.e., either β -D-galactosidase or β -D-glucuronidase) during growth and metabolism, wherein the inducer can comprise IPTG or methyl- β -D-glucuronide, and inhibitors of competing bacteria (see, for example, Abstract, col. 5, lines 1-20). Nelis beneficially teaches that after incubating the filter containing the bacteria in growth medium, the filter is removed from the growth medium and placed on an adsorbent cellulose pad impregnated with a medium to assay the marker enzyme. Nelis teaches that the medium used to assay the marker enzyme can be a chemiluminogenic substrate such as AMPGD (3-(4-methoxyspiro[(1,2-dioxetane-3,2'-tricyclo[3.3.1.1^{3,7}]decan)-4-yl)phenyl]- β -D-galactopyranoside), or derivatives thereof, and (3-(4-methoxyspiro[(1,2-dioxetane-3,2'-(5'-chloro)-tricyclo[3.3.1.1^{3,7}]decan)-4-yl)phenyl]- β -D-glucuronide), or derivatives thereof. In addition, Nelis teaches that the assay medium contains a membrane permeabilizer, preferably polymyxin B sulfate, colistin methanesulfonate, or a mixture of these with lysozyme. Furthermore, Nelis teaches that the membrane filter is sprayed with an accelerator to cause the colonies on the filter to become chemiluminescent, wherein the accelerator (i.e., enhancer) comprises a cationic polymer and an alkalinizing agent (see, for example col. 6, lines 1-60). Nelis further teaches that a luminometer may be used to measure overall light emission in detecting bacteria by chemiluminescence reactions (see, for example, col.3, lines 1-8). In addition, Nelis teaches that these methods may be used to either detect the presence of

coliform bacteria, or to determine the quantity of coliform bacteria, in a sample. In particular, Nelis teaches that enumeration of bacteria on the membrane filter is based on the chemiluminometric measurement of β -glucuronidase activity (see, for example, col. 7, lines 20-55).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Nelis, based upon the beneficial teachings provided by Nelis and with respect to the knowledge and teachings available to one of ordinary skill in the art. In particular, it would have been obvious to one of ordinary skill in the art at the claimed invention was made to provide a second filter means for separating the bacteria from the liquid culture, so as to concentrate the bacteria grown during the culturing and incubation step onto a filter for the enzymatic assay steps. One of skill in the art would have had the knowledge, skill, and motivation to provide this second filter means not expressly taught by Nelis because a second filtering step would concentrate bacteria from the first filter and liquid medium, and allow for better detection of bacteria from the sample. The result-effective adjustment of particular conventional working conditions (e.g., using a particular enhancing agent, and/or measuring luminescence in a particular manner) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of

ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments filed 23 December 2007 have been fully considered but they are not persuasive.

Applicant argues that Nelis relies only on counting of microcolonies and not the measurement of luminescence from a filter means. The Examiner respectfully disagrees with Applicant's argument because Nelis teaches in Example 5, col. 11, the superiority of ILM in enumeration of *E. coli* on a membrane filter based on chemiluminometric measurement of β -galactosidase activity (see Figure 9A). Furthermore, the Examiner disagrees with Applicant's argument because the instant claims (1, 3-7, 9-11, 13-16, 19-22, 25, 27, and 86) do not necessarily claim a method wherein the luminescence is measured.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a method wherein the luminescence is measured on a filter means) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, Applicant argues that the bacteria are transferred from the first filter means to a liquid broth and cultured in suspension then separated from the broth using

a second filter means. The Examiner notes that the instant specification clearly teaches that the "membrane filter may be present with the bacteria in the broth without any observed detrimental effect on the quantity of cells produced" (see specification, page 8). In addition, the Examiner points out that Nelis specifically teaches that the membrane filter containing the bacteria (after the step of concentrating the bacteria onto the membrane filter from the drinking water) may be placed into a liquid growth medium and then incubated, and then removed from the growth medium to assay the marker enzyme. One of skill in the art would recognize that if the membrane filter were incubated in liquid growth medium, it would be reasonable to filter the growth medium with a second membrane filter to concentrate any bacteria that would be in the medium onto a filter for assaying instead of leaving behind those bacteria.

In addition, Applicant's representative asserts that the present invention provides surprising evidence of the superior efficacy of the claimed method over the conventional colony counting techniques. Applicant is reminded that according to *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965) the "arguments of counsel cannot take the place of evidence in the record." Therefore, any arguments with respect to superior efficacy, etc. should be addressed in an appropriately filed affidavit or declaration.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

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APW
Examiner
Art Unit 1657

/Christopher R. Tate/
Primary Examiner, Art Unit 1655